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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,493	09/28/2001	Joseph Luber	MCP-0274	5286

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,493	LUBER ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination filed 02/25/05, and Amendment filed 12/22/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/25/05 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "the particle" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite particle size.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-6, 10 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Harbit US 3,108,046.

Harbit discloses a high dose tablet comprising from about 75% to about 98% drug and wax, such as paraffin wax or shellac wax (column 3, lines 1-31). The tablet dosage further comprises lubricant (column 4, lines 9-19). The dosage form provides both immediate release and sustained release (column 4, lines 21-31).

Claims 1 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. US 6,099,859.

Cheng discloses a controlled release oral tablet comprising from 75-95% drug and up to about 40% waxes (see column 3, lines 34-49; and column 5, lines 30-36). The tablet provides both, immediate release and controlled release (see column 5, lines 22-26). The tablet further comprises fatty acid, surfactant (flow aid), and chelating agent (column 3, lines 51-60), and can further be coated with a semipermeable membrane comprises cellulose derivatives polymer (see column 4, lines 11-44). Cheng also discloses the tablet is prepared by compression (see column 6, lines 35-41).

Claims 1, 2, 4-6, 10-12 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Robinson et al. US 6,270,790.

Robinson discloses a direct compressed tablet comprising up to about 60% by weight of at least one active ingredient, waxes and other excipients (see abstract, and column 5, lines 14-21). The active ingredient includes ibuprofen, acetaminophen, naproxen, aspirin, cetirizine, and mixtures thereof (column 2, lines 54-67). The tablet is suitable for immediate release and/or sustained release (column 3, lines 30-31).

Claims 1, 4-8 and 10-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. US 6,194,000.

Smith discloses an analgesic composition comprising immediate and controlled release forms (see abstract). The immediate release comprises up to 90% of the

analgesic agent, polyethylene glycol, waxes, and other carriers (column 2, lines 39-50; and column 3, lines 29-51). The dosage form provides from about 1-5000 mg/day of the analgesic agent (ID). The composition is in for oral administration in tablet or capsule or granule form (column 2, lines 55-67). Suitable coating to provide sustained release comprises cellulose derivatives polymer (column 4, lines 26-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al., or Robinson et al., or Smith et al., or Harbit, in view of Remon (WO 01/21155 A1).

Cheng, or Robinson, or Smith, or Harbit is relied upon for the reasons stated above. The references are silent as to the teaching of the same wax.

Remon discloses a rapidly disintegrating tablet comprising an active agent and wax particles (page 10, lines 14-18; page 19, lines 10-21). The wax is a microcrystalline wax or a natural wax (page 11, line 7 through page 15, line 8). The composition further contains disintegrants, swellable materials as well as other fillers (page 15, line 9 - page 18, line 6). The average size of the wax particles is from 0.5 to 2.0 mm (page 18, lines 7-18). The actives are chosen from a wide variety of known

pharmaceutical agents (page 19, line 22 - page 20, line 18). The composition also includes a film coating (page 21, line 4 - page 22, line 8). The tablets are produced by compression (page 23, lines 3-9). The tablets are rapid disintegration tablets (page 24, line 16 - page 25, line 1). Remon does not refer to the wax particles as powder. The Examiner refers to the Hawley's Condensed Chemical Dictionary, 12 Edition, 1993, pp. 960-61 as a reference of interest. The dictionary defines a powder as any solid, dry material of extremely small particle size. Being that most of the instant claims do not recite a particle size for the wax particles, the instant claims are deemed anticipated by Remon. Thus, it would have been obvious for one of ordinary skill in the art to modify the composition of Cheng, or Robinson, or Smith using the wax in view of the teaching of Remon, because Remon teaches tablet composition suitable in pharmaceutical art.

Regarding claim 16, Remon does not expressly teach the same particle size for the wax particles. However, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary particles sizes in tablet formulations. It is the position of the Examiner that this is limitation that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the ad at the time the invention was made.

Response to Arguments

Applicant's arguments filed 12/22/04 have been fully considered but they are not persuasive.

Applicant argues that Remon does not teach a swallowable immediate release tablet. At page 24, line 23 of Remon, it is taught that a solid agent for preparing an immediate release suspension. However, It is noted that the term "swallowable" is an intended use. The intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. It is further noted that nowhere in Remon teaches that the solid composition cannot be swallowed, or is prohibit from swallowing.

Applicant argues that it is not seen where Remon provides the requisite motivation to one of ordinary skill in the art for at least 60% of an active ingredient. In response to applicant's argument, the 102(a) rejection has been withdrawn. Remon is cited in view of Cheng, Robinson, Smith, or Harbit solely for the teaching of the wax particle. I it noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Appel et al., and Ting et al. are cited as of interest for the teachings of immediate release tablets.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Tran
Patent Examiner
AU 1615